IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COSMO TECHNOLOGIES LIMITED and SANTARUS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Cosmo Technologies Limited ("Cosmo") and Santarus, Inc. ("Santarus") (collectively, "Plaintiffs"), for their Complaint against Defendant Par Pharmaceutical, Inc. ("Par"), hereby allege as follows:

PARTIES

1. Plaintiff Cosmo is an Irish corporation, having its principal place of business at Connolly Building, 42-43 Amiens Street, Dublin, Ireland.

2. Plaintiff Santarus is a Delaware corporation, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, North Carolina 27615.

3. Upon information and belief, Par is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Ram Ridge Road, Spring Valley, NY 10977. On information and belief, Defendant Par develops, manufactures, and packages numerous generic versions of branded pharmaceutical products for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

4. This is a civil action for infringement of U.S. Patent No. 7,410,651 ("the '651 patent"); U.S. Patent No. 7,431,943 ("the '943 patent"); U.S. Patent No. 8,293,273 ("the '273 patent"); U.S. Patent No. 8,784,888 ("the '888 patent"); U.S. Patent No. 8,895,064 ("the '064 patent"); and U.S. Patent No. RE 43,799 ("the '799 patent") (collectively, "patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendant Par because Par is a corporation organized and existing under the laws of the State of Delaware and by virtue of, *inter alia*, having availed itself of the rights and benefits of Delaware law and having engaged in systematic and continuous contacts with the State of Delaware.

7. This Court further has personal jurisdiction over Defendant Par by virtue of, *inter alia*, the fact that Par has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including, *inter alia*, Plaintiff Santarus, which is a Delaware corporation.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

9. On August 12, 2008, the ’651 patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. A copy of the ’651 patent is attached hereto as Exhibit A.

10. Cosmo is the present owner of the ’651 patent. Santarus holds an exclusive license to the ’651 patent.

11. On October 7, 2008, the ’943 patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. A copy of the ’943 patent is attached hereto as Exhibit B.

12. Cosmo is the present owner of the ’943 patent. Santarus holds an exclusive license to the ’943 patent.

13. On October 23, 2012, the ’273 patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. A copy of the ’273 patent is attached hereto as Exhibit C.

14. Cosmo is the present owner of the ’273 patent. Santarus holds an exclusive license to the ’273 patent.

15. On July 22, 2014, the ’888 patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. A copy of the ’888 patent is attached hereto as Exhibit D.

16. Cosmo is the present owner of the ’888 patent. Santarus holds an exclusive license to the ’888 patent.

17. On November 25, 2014, the ’064 patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. A copy of the ’064 patent is attached hereto as Exhibit E.

18. Cosmo is the present owner of the ’064 patent. Santarus holds an exclusive license to the ’064 patent.

19. On November 13, 2012, the ’799 patent, titled “Controlled Release and Taste Masking Oral Pharmaceutical Composition,” was duly and legally issued. A copy of the ’799 patent is attached hereto as Exhibit F.

20. Cosmo is the present owner of the ’799 patent. Santarus holds an exclusive license to the ’799 patent.

ACTS GIVING RISE TO THIS ACTION

21. Santarus holds New Drug Application (“NDA”) No. 203634 for oral tablets containing 9 mg of the active ingredient budesonide, which are sold in the United States under the brand name “Uceris®.” Uceris® is indicated for the treatment of mildly to moderately active ulcerative colitis.

22. Pursuant to 21 U.S.C. § 355(b)(1), the ’651 patent, the ’943 patent, the ’273 patent, the ’888 patent, the ’064 patent and ’799 patent are listed in the Food and Drug Administration’s (“FDA”) publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the “Orange Book”) as covering Uceris® and its use.

23. Upon information and belief, Par submitted ANDA No. 206131 (“Par’s ANDA”) to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Par’s ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 9 mg

of budesonide ("Par Generic Product") prior to the expiration of the '651 patent, the '943 patent, the '273 patent, the '888 patent, the '064 patent, and the '799 patent.

24. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Par certified in ANDA No. 206131, *inter alia*, that the claims of the '651 patent, the '943 patent, the '273 patent, the '888 patent, the '064 patent and the '799 patent are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, offer for sale, or sale of the proposed Par Generic Product.

25. Plaintiffs received written notification of Par's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated December 19, 2014 ("Par's Notice Letter") and sent via Federal Express.

26. This action was commenced by Plaintiffs within 45 days of the date of Par's Notice Letter.

27. Par's Notice Letter included an accompanying Offer of Confidential Access ("OCA") to certain Par confidential information regarding the Par Generic Product. Plaintiffs subsequently, over the course of several weeks, negotiated with Par in an effort to agree on reasonable terms for Par's OCA. The parties were not able to reach agreement with respect to the revisions to the terms of Par's OCA that Plaintiffs proposed.

28. To date, Par has not provided Plaintiffs with a copy of any portions of its ANDA or any information regarding the Par Generic Product, beyond the information that was set forth in Par's Notice Letter.

29. The limited information relating to the Par Generic Product that was provided in Par's Notice Letter does not demonstrate that the Par Generic Product that Par is asking the FDA to approve for sale will not fall within the scope of any issued claim of the

'651 patent, the '943 patent, the '273 patent, the '888 patent, the '064 patent, or the '799 patent.

FIRST COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 7,410,651

30. Plaintiffs re-allege paragraphs 1-29 as if fully set forth herein.

31. Par's submission of ANDA No. 206131 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '651 patent under 35 U.S.C. § 271(e)(2)(A).

32. Moreover, if Par manufactures, uses, sells, offers for sale, or imports into the United States any of the Par Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '651 patent, including any applicable exclusivities or extensions, Par would further infringe the '651 patent under 35 U.S.C. § 271(a), (b), and/or (c).

33. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 206131 be a date that is not earlier than the expiration of the term of the '651 patent, including any extension(s) granted by the United States Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '651 patent to which Plaintiffs are or become entitled.

34. Plaintiffs will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

35. Upon information and belief, Par was aware of the existence of the '651 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '651 patent constituted an act of infringement of the '651 patent.

SECOND COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 7,431,943

36. Plaintiffs re-allege paragraphs 1-35 as if fully set forth herein.

37. Par's submission of ANDA No. 206131 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '943 patent under 35 U.S.C. § 271(e)(2)(A).

38. Moreover, if Par manufactures, uses, sells, offers for sale, or imports into the United States any of the Par Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '943 patent, including any applicable exclusivities or extensions, Par would further infringe the '943 patent under 35 U.S.C. § 271(a), (b), and/or (c).

39. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 206131 be a date that is not earlier than the expiration of the term of the '943 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '943 patent to which Plaintiffs are or become entitled.

40. Plaintiffs will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

41. Upon information and belief, Par was aware of the existence of the '943 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '943 patent constituted an act of infringement of the '943 patent.

THIRD COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 8,293,273

42. Plaintiffs re-allege paragraphs 1-41 as if fully set forth herein.

43. Par's submission of ANDA No. 206131 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '273 patent under 35 U.S.C. § 271(e)(2)(A).

44. Moreover, if Par manufactures, uses, sells, offers for sale, or imports into the United States any of the Par Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '273 patent, including any applicable exclusivities or extensions, Par would further infringe the '273 patent under 35 U.S.C. § 271(a), (b), and/or (c).

45. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 206131 be a date that is not earlier than the expiration of the term of the '273 patent, including any extension(s) granted by the United States Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '273 patent to which Plaintiffs are or become entitled.

46. Plaintiffs will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

47. Upon information and belief, Par was aware of the existence of the '273 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '273 patent constituted an act of infringement of the '273 patent.

FOURTH COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 8,784,888

48. Plaintiffs re-allege paragraphs 1-47 as if fully set forth herein.

49. Par's submission of ANDA No. 206131 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '888 patent under 35 U.S.C. § 271(e)(2)(A).

50. Moreover, if Par manufactures, uses, sells, offers for sale, or imports into the United States any of the Par Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '888 patent, including any applicable exclusivities or extensions, Par would further infringe the '888 patent under 35 U.S.C. § 271(a), (b), and/or (c).

51. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 206131 be a date that is not earlier than the expiration of the term of the '888 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '888 patent to which Plaintiffs are or become entitled.

52. Plaintiffs will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

53. Upon information and belief, Par was aware of the existence of the '888 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '888 patent constituted an act of infringement of the '888 patent.

FIFTH COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. 8,895,064

54. Plaintiffs re-allege paragraphs 1-53 as if fully set forth herein.

55. Par's submission of ANDA No. 206131 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '064 patent under 35 U.S.C. § 271(e)(2)(A).

56. Moreover, if Par manufactures, uses, sells, offers for sale, or imports into the United States any of the Par Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '064 patent, including any applicable exclusivities or extensions, Par would further infringe the '064 patent under 35 U.S.C. § 271(a), (b), and/or (c).

57. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 206131 be a date that is not earlier than the expiration of the term of the '064 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '064 patent to which Plaintiffs are or become entitled.

58. Plaintiffs will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

59. Upon information and belief, Par was aware of the existence of the '064 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '064 patent constituted an act of infringement of the '064 patent.

SIXTH COUNT
INFRINGEMENT BY PAR OF U.S. PATENT NO. RE 43,799

60. Plaintiffs re-allege paragraphs 1-59 as if fully set forth herein.

61. Par's submission of ANDA No. 206131 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '799 patent under 35 U.S.C. § 271(e)(2)(A).

62. Moreover, if Par manufactures, uses, sells, offers for sale, or imports into the United States any of the Par Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '799 patent, including any applicable exclusivities or extensions, Par would further infringe the '799 patent under 35 U.S.C. § 271(a), (b), and/or (c).

63. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 206131 be a date that is not earlier than the expiration of the term of the '799 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '799 patent to which Plaintiffs are or become entitled.

64. Plaintiffs will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

65. Upon information and belief, Par was aware of the existence of the '799 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '799 patent constituted an act of infringement of the '799 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Par has infringed one or more claims of the '651 patent;

B. That Par has infringed one or more claims of the '943 patent;

C That Par has infringed one or more claims of the '273 patent;

D That Par has infringed one or more claims of the '888 patent;

E That Par has infringed one or more claims of the '064 patent;

F That Par has infringed one or more claims of the '799 patent;

G. That pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 206131 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;

H. That Par, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, or importing into the United States the Par Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '651 patent, the '943 patent, the '273 patent, the '888 patent, the '064 patent, and the '799 patent prior to their expiration, including any applicable exclusivities or extensions to which Plaintiffs are or become entitled;

I. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action; and

J. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

OF COUNSEL:

Bruce M. Wexler
Joseph M. O'Malley, Jr.
Melanie R. Rupert
David M. Conca
Leonard A. Monfredo II
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

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